

REMARKS/ARGUMENTS

Claims 1-20 and 15-18 have been rejected. Claims 11-14 and 19-22 are withdrawn from consideration. Claims 3-5, 7, and 17-18 have been cancelled without prejudice to or disclaimer of the subject matter encompassed thereby in order to further prosecution of this application. Applicants expressly reserve the right to file continuing applications or take other such appropriate measures to seek protection for the inventions encompassed by the cancelled subject matter.

Claims 6, 8-9, and 15 have been amended for clarity and claims 23-32 have been added in order to specify the types of ventricular fibrillation to be treated by the method of claims 15 or 16 and to remove reference to tables in previous claims 4 and 5. Support for these claim amendments may be found throughout the specification and in the original claims. Accordingly, no new matter has been introduced by way of these claim amendments or newly added claims.

Claims 1-2, 6, 8-10, 15-16, and 23-32 are currently under examination in the application. Reexamination and reconsideration of the claims are respectfully requested in view of the following remarks. The Examiner's comments in the Office Action dated March 29, 2007 are addressed below in the order set forth therein.

The Rejection of the Claims Under 35 U.S.C. §§101 and 112, First Paragraph, Should Be Withdrawn

The Examiner has rejected claims 1-10, 17, and 18 for allegedly failing to comply with the written description requirement and for allegedly failing to be supported by either an asserted or well established utility. The basis for these rejections is the Examiner's assertion that ventricular fibrillation cannot be prevented. The Examiner states that "[t]here is no evidence that one could prevent ventricular fibrillation by consuming the claimed *Trichilia spp.*" (see pages 2-3 of the Office Action dated March 29, 2007).

Applicants submit concurrently herewith a Rule 37 C.F.R. § 1.132 Declaration of Dr. Irineu Tadeu Velasco, in which data is provided supporting the methods set forth in the present claims relating to prevention of ventricular fibrillation with the prolonged use of *Trichilia*

catigua. In particular, the declaration provides data from a study involving the use of *Trichilia catigua* when there are no antecedents of ventricular fibrillation, and demonstrate that such use protects the hearts of rabbits from induction of ventricular fibrillation. In other words, the data demonstrate that ventricular fibrillation can be prevented. Accordingly, Applicants request that these rejections be withdrawn.

The Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

The Examiner has rejected claims 4 and 5 for being indefinite for using tables and reciting “generic” and “preferred”. Claims 4 and 5 have been cancelled and new claims 27 to 32 have been introduced in which the various components described in the tables are written out in single claim sentences. Accordingly, Applicants submit that this rejection has been obviated and request that it be withdrawn.

The Rejection of the Claims Under 35 U.S.C. § 102(a) Should Be Withdrawn

The Examiner has rejected claims 1, 2, 8, and 18 for allegedly being anticipated by Batista *et al.* (WO 200296443). The Examiner states that Batista *et al.* teach a method for treating acute myocardial infarction with a composition comprising *Trichilia catigua*, *Paullinia cupana*, and *Zingiber officinale*, and that this disclosure anticipates the above-referenced claims as they relate to “preventing” ventricular fibrillation. This rejection is respectfully traversed for the reasons provided below.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Here, because the Batista *et al.* contains no reference whatsoever to ventricular fibrillation, it appears that the Examiner is basing this rejection on the premise that treatment of patients with acute myocardial infarction inherently anticipates the prevention of ventricular fibrillation. However, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). Inherency may not be established by probabilities or

possibilities; the mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Applicants respectfully submit that the Examiner has failed to meet this requirement and has failed to provide a solid basis for the contention that prevention of ventricular fibrillation necessarily flows from treatment of myocardial infarction. Accordingly, Applicants request that this rejection be withdrawn.

The Rejections of the Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn

The Examiner has rejected claims 1-8 and 18 for allegedly being obvious in view of the combination of Andre *et al.* (WO200296441) and Sander *et al.* (US 6,335,039). This rejection is traversed for the reasons provided below.

The rejected claims are drawn to the treatment or prevention of ventricular fibrillation. The Examiner has acknowledged that neither Andre *et al.* nor Sander *et al.* explicitly teach the treatment of ventricular fibrillation (page 6 of the Office Action dated March 29, 2007). Both Andre *et al.* and Sander *et al.* teach methods for producing vasodilation using *Trichilia* and other plants. However, there is no teaching or suggestion in Andre *et al.* or Sander *et al.* of the treatment or prevention of ventricular fibrillation. One of the necessary elements for establishing a *prima facie* case of obviousness is that the prior art references must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Accordingly, Applicants submit that such a *prima facie* case of obviousness has not been established.

Because neither Andre *et al.* nor Sander *et al.* teach or suggest treatment or prevention of ventricular fibrillation, a *prima facie* case of obviousness has not been established. Applicants therefore request that this rejection be withdrawn.

The Examiner has also rejected claims 1-10 and 15-18 for allegedly being obvious in view of the combination of Andre *et al.* and Sander *et al.*, further in view of Kowey *et al.*

(*Cardiovascular Res.* 17:106-112 (1982)). This rejection is respectfully traversed for the reasons provided below.

As described above, neither Andre *et al.* nor Sander *et al.* teach or suggest treatment or prevention of ventricular fibrillation. The Examiner cites Kowey *et al.* on the basis that this reference allegedly teaches that ventricular fibrillation can be abolished by pretreatment with vasodilators. The Examiner therefore contends that one of ordinary skill in the art would have been motivated on the basis of Kowey *et al.* to modify the teachings of Andre *et al.* and Sander *et al.* to arrive at the current claims.

To establish a *prima facie* case of obviousness, another necessary element is that there must be a reasonable expectation of success. *Id.* In the present case, the term “vasodilator” encompasses a wide range of structurally distinct compounds, and one of skill in the art would not have a reasonable expectation that all vasodilators would be successful in the Kowey *et al.* methods. This is confirmed by Kowey *et al.*, who state that although they observed protective effects of prostacyclin, prostaglandin E₁, and nitroglycerin on vulnerability to ventricular fibrillation, “[i]t remains to be determined whether other vasodilator drugs possess a similar potential for protection against malignant arrhythmia” (see Conclusion on page 111 of Kowey *et al.*). Accordingly, Applicants submit that a *prima facie* case of obviousness has not been established.

Because one of skill in the art would not have a reasonable expectation of success in the use of *Trichilia* within the methods of Kowey *et al.*, a *prima facie* case of obviousness has not been established. Applicants therefore request that this rejection be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §§112, First and Second Paragraphs, 101, 102(a), and 103(a) are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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